

PRIOR AUTHORIZATION POLICY

POLICY: Ophthalmic for Dry Eye Disease – Eysuvis Prior Authorization Policy

- Eysuvis™ (loteprednol etabonate 0.25% ophthalmic suspension – Kala Pharmaceuticals)

REVIEW DATE: 12/09/2020

OVERVIEW

Eysuvis, an ophthalmic corticosteroid, is indicated for the **short-term (up to 2 weeks) treatment of the signs and symptoms of dry eye disease.**¹

Eysuvis is a topical, anti-inflammatory, nanoparticle suspension of loteprednol etabonate with proprietary mucus-penetrating particle technology synthesized through structural modifications of prednisolone-related compounds so that it will undergo a predictable transformation to an inactive metabolite.^{1,2} Eysuvis inhibits the edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation.

Guidelines

Eysuvis is not addressed in guidelines. The American Academy of Ophthalmology (AAO) published a Preferred Practice Pattern® (2018) for the treatment of dry eye syndrome.³ Some risk factors for dry eye syndrome include aging, female gender, decrease in supportive factors such as androgen hormones, radiation therapy, surgeries that disrupt the trigeminal afferent sensory nerves (e.g., laser-assisted in situ keratomileusis [LASIK]) or systemic inflammatory conditions such as rheumatoid arthritis. For mild dry eyes, education and environmental modifications, artificial tear solutions and eyelid therapy (warm compresses and eyelid scrubs) are listed as some of the treatment options. Guidelines noted a commercially available loteprednol etabonate 0.5% was used in a prospective, randomized study for a 2-week period. The study found a favorable effect in patients' dry eye symptoms and conjunctival hyperemia findings, but not in ocular surface staining, Schirmer test results, or use of artificial tears.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Eysuvis. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Eysuvis is recommended in those who meet the following criteria:

FDA-Approved Indications

- 1. Dry Eye Disease (Short-term Treatment).** Approve for 1 month if the patient meets the following (A and B):
 - A) Patient has tried artificial tears; AND
 - B) Patient has tried one other formulation of ophthalmic loteprednol etabonate.
Note: Examples of other ophthalmic loteprednol etabonate formulations include Alrex® 0.2% suspension, Inveltys® 1% suspension, loteprednol etabonate 0.5% suspension (Lotemax®, generics), Lotemax® 0.5% gel, Lotemax® SM 0.38% gel, and Lotemax® 0.5% ointment.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Eysuvis is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Eysuvis® ophthalmic suspension [prescribing information]. Watertown, MA: Kala Pharmaceuticals; October 2020.
2. Korenfeld M, Nichols KK, Goldberg D, et al. Safety of KPI-121 ophthalmic suspension 0.25% in patients with dry eye disease: a pooled analysis of 4 multicenter, randomized, vehicle-controlled studies. *Cornea*. 2020 August 19. [Online ahead of print].
3. American Academy of Ophthalmology cornea/external disease panel. Preferred Practice Pattern® Guidelines. Dry eye syndrome. San Francisco, CA: American Academy of Ophthalmology; 2018. Available at: www.aao.org/ppp. Accessed on October 29, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/09/2020